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## THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group: 3738

Certificate Under 37 CFR 1.8(a)

Confirmation No.: 9094

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addressed to Assistant Commissioner for Patents,  
Washington, D.C. 20231

Application No.: 10/044,031

on November 13, 2002

Invention: Purified Submucosa Graft Material

Applicant: Stephen F. Badylak

}   
(Signature)

Filed: January 11, 2002

} Garla L. Twyman  
(Printed Name)

Attorney

Docket: 3220-69262

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Examiner: Unknown

NOV 25 2002

TECHNOLOGY CENTER R3700

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

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Sir:

This statement is filed in the application identified above pursuant to 37 C.F.R. § 1.56. Some of the references disclosed herein were cited in U.S. Patent Application No. 08/916,490 (now U.S. Patent No. 6,206,931) to which the captioned application claims priority. Accordingly, copies of the references cited in the '931 patent are not provided with this Information Disclosure Statement. Patent references BD through DD and references AX through AZ were not cited in the '931 patent and copies of these references are transmitted herewith.

No representation is intended that a complete search has been made of the prior art or that no better art references than listed below are available. The filing of this Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in §1.56(b).

None of the cited art is believed to disclose or suggest the invention recited in the claims of the above-identified application. It is therefore believed that the claimed invention is patentably distinguishable over these references.

Applicants believe that no fees are required with this statement. The Assistant Commissioner is hereby authorized to charge any fees which may be required or credit any overpayment to our Deposit Account No. 10-0435, with reference to our matter 3220-69262. A duplicate copy of this paper is enclosed for that purpose.

Respectfully submitted

  
Steven R. Lammert  
Registration No. 27,653  
Attorney for Applicants

SRL:glt  
Indianapolis, Indiana 46204  
317-231-7258



PATENT AND TRADEMARK OFFICE  
NOV 18 2002 INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
3220-69262

SERIAL No.  
10/044,031

APPLICANT  
Badylak, et al.

FILING DATE  
January 11, 2002

GROUP  
Unknown

U.S. PATENT DOCUMENTS

*Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if
	AA	3,810,473	May 14, 1974	Cruz et al.			
	AB	4,578,067	Mar. 25, 1986	Cruz			
	AC	4,902,508	Feb. 20, 1990	Badylak, et al.			
	AD	4,956,178	Sept. 11, 1990	Badylak, et al.			
	AE	5,028,695	July 2, 1991	Eckmayer, et al.			
	AF	5,275,826	Jan. 4, 1994	Badylak, et al.			<b>RECEIVED</b>
	AG	5,336,616	Aug. 9, 1994	Livesey, et al.			
	AH	5,372,821	Dec. 13, 1994	Badylak, et al.			<b>NOV 25 2002</b>
	AI	5,437,287	Aug. 1, 1995	Phillips, et al.			
	AJ	5,460,962	Oct. 24, 1995	Kemp			<b>TECHNOLOGY CENTER R3700</b>
	AK	5,480,424	Jan. 2, 1996	Cox			

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		Document Number	Date	Country	Class	Subclass	Translation Yes No
	AL	WO 90/00395	Jan. 25, 1990	PCT			<b>RECEIVED</b>
	AM	WO 93/05798	Apr. 1, 1993	PCT			
	AN	WO 96/25179	Aug. 22, 1996	PCT			<b>DEC 05 2002</b>
	AO	WO 96/31157	Oct. 10, 1996	PCT			<b>OFFICE OF PETITIONS</b>
	AP						

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices; Dec. 1987, Prepared by Center for Drug Evaluation and Research, Center for Biologic Evaluation and Research, Center for Devices and Radiological Health, and Center for Veterinary Medicine.
AS	Hodde, J. P. et al.; "Glycosaminoglycan Content of Small Intestinal Submucosa: A Bioscaffold for Tissue Replacement" <i>Tissue Engineering</i> , vol. 2, No. 3, 1996, pp. 209-217, XP002063373.
AT	Badylak, S. F. et al.; "The Use of Xenogeneic Small Intestinal Submucosa as a Biomaterial for Achille's Tendon Repair in a Dog Model"; <i>Journal of Biomedical Materials Research</i> , vol. 29, No. 8, 1995, pp. 977-985, XP002071882.
AU	Cobb, M.A. et al.; "Histology After Dural Grafting With Small Intestinal Submucosa", <i>Surgical Neurology</i> , vol. 46, No. 4, 1996, pp. 389-394, XP002071883.
AV	Vaught, J.D. et al.; "Detrusor Regeneration in the Rat Using Porcine Small Intestinal Submucosal Grafts: Functional Innervation and Receptor Expression", <i>The Journal of Urology</i> , vol. 155, No. 1, 1996, pp. 374-378, XP002071884.
AW	Baldry, M.G.C. and Fraser, J.A.L.; Disinfection with Peroxygens; United Kingdom; pp. 91-116.
AX	"Biological Evaluation of Medical Devices-Part 1: Guidance on Selection of Tests," American National Standards, Inc., ANSI/AAMI 10993-1, pp. 13-14 (1994).
AY	"Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices," ASTM F 748-91, pp. 198-201 (1991).
AZ	"Guidance Document for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Intra-Articular Prosthetic Knee Ligament Devices," USFDA Center for Devices and Radiological Health, pp. 1-40 (1987).

Examiner	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

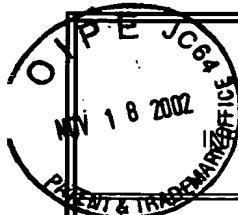
 <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE STATEMENT</b>				ATTY. DOCKET NO. 3220-69262		SERIAL No. 10/044,031	
				APPLICANT Badylak, et al.			
				FILING DATE January 11, 2002			
						GROUP Unknown	
<b>U.S. PATENT DOCUMENTS</b>							
*Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if
	BA	5,507,810	Apr. 16, 1996	Prewett, et al.			
	BB	5,733,337	Mar. 31, 1998	Carr, et al.			
	BC	5,782,914	July 21, 1998	Schankereli			
	BD	4,978,668	Dec. 18, 1990	Babbs et al.			
	BE	5,007,927	Apr. 16, 1991	Badylak et al.			
	BF	5,281,422	Jan. 25, 1994	Badylak et al.			
	BG	5,352,463	Oct. 4, 1994	Badylak et al.			
	BH	5,354,274	Oct. 11, 1994	Demeter et al.			
	BI	5,445,833	Aug. 29, 1995	Badylak et al.			
	BJ	5,516,533	May 14, 1996	Badylak et al.			
	BK	5,554,389	Sept. 10, 1996	Badylak et al.			
<b>FOREIGN PATENT DOCUMENTS</b>							
		Document Number	Date	Country	Class	Subclass	Translation Yes No
	BL						
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<b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
	BR						
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			FILING DATE January 11, 2002		GROUP Unknown		
<b>U.S. PATENT DOCUMENTS</b>							
*Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if
	CA	5,573,784	Nov. 12, 1996	Badylak et al.			
	CB	5,641,518	June 24, 1997	Badylak et al.			
	CC	5,645,860	July 8, 1997	Knapp, Jr. et al.			
	CD	5,695,998	Dec. 9, 1997	Badylak et al.			
	CE	5,711,969	Jan. 27, 1998	Patel et al.			
	CF	5,753,267	May 19, 1998	Badylak et al.			
	CG	5,755,791	May 26, 1998	Whitson et al.			RECEIVED NOV 25 2002
	CH	5,762,966	June 9, 1998	Knapp, Jr. et al.			
	CI	5,866,414	Feb. 2, 1999	Badylak et al.			TECHNOLOGY CENTER R3700
	CJ	5,885,619	Mar. 23, 1999	Patel et al.			
	CK	5,955,110	Sept. 21, 1999	Patel et al.			
<b>FOREIGN PATENT DOCUMENTS</b>							
		Document Number	Date	Country	Class	Subclass	Translation Yes No
	CL						
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	CN						
	CO						
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<b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
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				FILING DATE January 11, 2002			GROUP Unknown
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*Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if
	DA	5,968,096	Oct. 19, 1999	Whitson et al.			
	DB	5,997,575	Dec. 7, 1999	Whitson et al.			
	DC	6,087,157	July 11, 2000	Badylak et al.			
	DD	6,171,344	Jan. 9, 2001	Atala			
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	DF				NOV 25 2002		
	DG				TECHNOLOGY CENTER 3700		
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FOREIGN PATENT DOCUMENTS							
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Examiner						Date Considered	
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